K073112

Section II

AUG - 1 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Date	Nov 02, 2007
Submitter	Intuitive Surgical®, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Michael Yramategui Sr. Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 E-mail: mike.yramategui@intusurg.com
Subject Device	Trade Name(s): da Vinci SonicPro Cleaning System Classification Name: Medical Washer Common Name: Medical Washer, Automated Washer, Automated Cleaner, Cleaning System Device Class: Class II (NVE)

Predicate Devices	K043314 Manzi Cleaner System Langford IC Systems, Inc. K063220, K021036 Intuitive Surgical *EndoWrist* Endoscopic Instruments and Accessories cleared for use with da Vinci and da Vinci S Surgical Systems Intuitive Surgical, Inc.
Device Description	The da Vinci SonicPro Cleaning System is intended for the automated cleaning of the reusable *EndoWrist* Instruments and Accessories only. The cleaning system is intended to provide an automated method for the cleaning step as part of the reprocessing procedure for the Intuitive Surgical *EndoWrist* Instruments and Accessories. This system is not intended to perform disinfection. The SonicPro Cleaning System is a floor standing model comprised of an ultrasonic tank, fluid pumps, flushing tubing, various sensors and controllers, and a basket to hold the devices intended to be cleaned using this system. Using pressurized water, an enzymatic cleaning agent and ultrasonic agitation, the SonicPro provides an automated cleaning process. Effective cleaning of the *EndoWrist* Instruments and Accessories is achieved through qualified and controlled process parameters, and pre-programmed cycle configurations. After completion of the cleaning cycle, the devices are to be removed from the cleaning system, dried and further prepared for sterilization. The SonicPro cleaning system has been tested for use ONLY with the Intuitive Surgical® devices as detailed in the instructions for use document provided with the cleaning system.
Intended Use	The da Vinci® SonicPro™ Cleaning System is intended for the automated cleaning of reusable *EndoWrist* Instruments and Accessories used with the da Vinci and da Vinci S surgical systems. The Cleaning System when used in accordance with its labeling provides an automated cleaning method as part of the re-processing sequence for the *EndoWrist* Instruments and Accessories.

Comparison to Predicate Device	Based on the comparison of design, technology, principle, mechanism and method of use, the da Vinci SonicPro Cleaning System is substantially equivalent to similar automated washers as previously cleared by FDA (K043314). Based on cleaning efficacy, steps and process parameters of the cleaning cycle, the SonicPro Cleaning System is equivalent to the currently used manual cleaning method for reprocessing of *EndoWrist* Instruments and Accessories cleared under K063220 and K021036.
Technological Characteristics	The technological characteristics and mechanisms of the subject da Vinci SonicPro Cleaning System is equivalent to the predicate device. The SonicPro automated cleaning system uses similar principles and parameters as the predicate manual cleaning method. This system does not incorporate any new technological characteristics.
Performance Data	Design analysis and testing is conducted to confirm that basic functional characteristics of the subject devices are substantially equivalent to the predicate device cited, and that design output meets the design input requirements. Simulated-Use test is conducted to evaluate the cleaning efficacy of the SonicPro Cleaning System in effectively cleaning the devices intended to be used with the system.
Conclusion	Based upon available technical information, intended use and performance information provided in this pre-market notification, the da Vinci SonicPro Cleaning System described herein is substantially equivalent to current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2008

Intuitive Surgical, Inc.
% Mr. Michael H. Yramategui
Principal Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K073112
Trade/Device Name: da Vinci SonicPro Cleaning System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NVE
Dated: July 30, 2008
Received: August 1, 2008

Dear Mr. Yramategui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section III

Indications for Use

510(k) Number (if known): k073112

Device Name: da Vinci SonicPro Cleaning System

Indications for Use:

The da Vinci® SonicPro™ Cleaning System is intended for the automated cleaning of reusable *EndoWrist* Instruments and Accessories used with the da Vinci and da Vinci S surgical systems. The Cleaning System when used in accordance with its labeling provides an automated cleaning method as part of the re-processing sequence for the *EndoWrist* Instruments and Accessories.

Prescription Use_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use__X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of device Evaluation (ODE)

Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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